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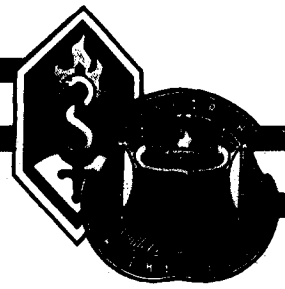

Test and Evaluation Report of the Physio Control Defibrillator/Monitor Model LIFEPAK® 10

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The Physio Control Defibrillator/Monitor Model LIFEPAK® 10 was tested for electromagnetic interference/compatibility in the UH-60A helicopter under the U.S. Army Program for Testing and Evaluation of Equipment for Aeromedical Operations. The tests were conducted using current military and industrial standards and procedures for electromagnetic interference/compatibility and human factors. The LIFEPAK® 10 passed the overall evaluation and is validated as compatible with U.S. Army aeromedical aircraft.

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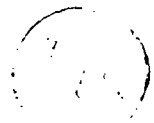

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Section 1. Executive digest

The Army program for Test and Evaluation of Aeromedical Equipment uses existing military standards (MIL-STD) and collective professional expertise to test and evaluate selected medical equipment proposed for use aboard Army aircraft. Equipment meeting these standards ensures the safety of the crew, patients, and aircraft by eliminating risks due to: (1) interference by the medical equipment with aircraft systems/subsystems operation, (2) the aircraft system's interference with the operation of the medical equipment, (3) the medical equipment's susceptibility to environmental exposure, or (4) physical and/or functional incompatibility while in use on board selected rotary-wing aircraft. This program tests both developmental and nondevelopmental (off the shelf) medical equipment destined for use aboard Army aeromedical aircraft.

1.1 TEST OBJECTIVES

1.1.1 To determine if the medical equipment is complete and operational per the manufacturer's operating instructions.

1.1.2 To ensure the electrical safety of the medical equipment.

1.1.3 To ensure the equipment will function as designed throughout the rated battery operation time.

1.1.4 To ensure the safety of the operator, the patient, and the aircrew.

1.1.5 To assess design considerations which potentially could contribute to an operator error.

1.1.6 To determine if the medical equipment can function as designed in a low pressure environment.

1.1.7 To determine the ability of the medical equipment to withstand the vibrational stresses expected in a rotary-wing flight environment without degradation or malfunction.

1.1.8 To determine the ability of the medical equipment to be stored and operated in a high temperature environment.

1.1.9 To determine the ability of the medical equipment to be stored and operated in a low temperature environment.

1.1.10 To determine the ability of the medical equipment to operate satisfactorily for short periods during exposure to highly humid conditions.

1.1.11 To assess the levels of electromagnetic emissions produced by the medical equipment within selected frequency ranges.

1.1.12 To assess the minimum electromagnetic susceptibility levels of the medical equipment within selected frequency ranges.

1.1.13 To assess the physical and/or functional compatibility of the medical equipment while in use on board the aircraft.

1.1.14 To assess the electromagnetic interference (EMI) and electromagnetic compatibility (EMC) characteristics of the medical equipment with the host aircraft and its installed systems.

1.2 TESTING AUTHORITY

Research and Technology Work Unit Summary, dated 5 October 1989. Project number 3M462907D836, titled, Army Program for Testing and Evaluation of Equipment for Aeromedical Operations.

1.3 SCOPE

1.3.1 This test was conducted at the United States Army Aeromedical Research Laboratory (USAARL), Cairns Army Airfield (CAAF), and designated test flight areas in and around Fort Rucker, Alabama.

1.3.2 The USAARL UH-60A aircraft, serial number 88-26069, with subsystems delineated in paragraph 3.2.2, was configured with the Physio Control defibrillator/monitor, model LIFEPAK® 10 and used as the test aircraft for the in-flight evaluation. The in-flight evaluation required 4.3 flight hours.

1.3.3 Laboratory testing was accomplished at USAARL using government furnished equipment (GFE) by Universal Energy Systems, Inc. (UES), under contract No. DAMD 17-86-C-6215.

1.3.4 Prior to flight testing, the following tests were accomplished: Acceptance inspection, equipment training, electromagnetic compatibility, human factors and safety, environmental compatibility, and in-flight compatibility.

1.3.5 An airworthiness release (AWR) dated 27 December 1990 was received from the U.S. Army Aviation Systems Command (AVSCOM) prior to the in-flight testing of the LIFEPAK® 10.

1.4 MATERIAL DESCRIPTION

The Physio Control LIFEPAK® 10 is a portable defibrillator, monitor, and optional noninvasive pacer. It is battery powered and contains both a cathode ray tube (CRT) cardioscope, which

displays real time electrocardiographs (ECG), and two defibrillator paddles which may discharge any of nine selectable energy levels.

1.5 SUMMARY

1.5.1 Laboratory testing

1.5.1.1 Battery Life Evaluation: The LIFEPAK® 10 performed longer than the manufacturer specification of 45 minutes of operation with a fully charged battery. Although no recharge time was specified in the manufacturer's manuals, the batteries were recharged in 90 minutes in the laboratory.

1.5.1.2 Electrical Safety Evaluation: All measurements were within acceptable limits. No unsafe qualities were found in the LIFEPAK® 10. The limits for currents and resistances were in accordance with the National Fire Prevention Association (NAFP) standards.

1.5.1.3 Human Factors Evaluation: The LIFEPAK® 10 was found to be unsatisfactory in the conductor criteria. The cables connecting the defibrillator paddles interfere with the replacement of the paddles in their storage holders. Standards referenced include MIL-STD-1472D, McCormick's HFE Guide, and UL-544.

1.5.1.4 Environmental Tests: The LIFEPAK® 10 can be expected to perform in a variety of environmental conditions. Its performance was found to be satisfactory in all stages of the environmental testing. The requirements for environmental tests are established in MIL-STD-810D, methods 500.2 (altitude), 514.3 (vibration), 501.2 (high temperature), 502.2 (low temperature), and 507.2 (humidity).

1.5.1.5 Radiated Emissions Tests (RE02): The LIFEPAK® 10 may be unsatisfactory for use in certain EMI sensitive environments. Narrowband (NB) and broadband (BB) radiated emissions were detected in the test frequency ranges. Some narrowband and broadband emissions exceeded the test limits. Emission limits are set forth in MIL-STD-461, Notice 4.

1.5.1.6 Radiated Susceptibility Test (RS03): The LIFEPAK® 10 was not found to be susceptible to the radiated interference levels in this test. Testing was not performed in the frequency range 10 kHz to 200 MHz due to the "in repair status" of the transmitter amplifier used for this range of testing.

1.5.2 In-flight testing

1.5.2.1 During the in-flight human factors evaluation, the LIFEPAK® 10 was found to be satisfactory in all but two cate-

gories of the evaluation criteria. First, the human factors deficiency noted in the laboratory evaluation (paragraph 1.5.1.3) was exacerbated by the cramped quarters in the aircraft. Second, the inability of the flight surgeon to hear the audio alarms while wearing the required flight ensemble and the environmental noise produced by the aircraft precludes the use of the audio alarms.

1.5.2.2 The aircraft and its subsystems were not adversely affected by the operation of the LIFEPAK® 10 in any of the prescribed flight test modes.

1.5.2.3 The LIFEPAK® 10 was not affected by the aircraft and its subsystems during the in-flight testing.

1.6 CONCLUSIONS

Based on the combination of laboratory and in-flight testing, the LIFEPAK® 10 is validated as compatible with U.S. Army aeromedical UH-60A Blackhawk with the subsystems listed in paragraph 3.2.2. The LIFEPAK® 10 must be restricted to battery use only.

SECTION 2. SUBTESTS

2.1 INITIAL INSPECTION

2.1.1 Objective

To determine if the LIFEPAK® 10 is complete and operational for testing per the manufacturer's operating instructions.

2.1.2 Criteria

2.1.2.1 The physical inventory is conducted solely for investigation and documentation.

2.1.2.2 The LIFEPAK® 10 will display a consistent and accurate measurement of simulated ECG signals within ± 2 percent and deliver the programmed defibrillator energy within 1 percent.

2.1.3 Test procedure

2.1.3.1 A complete physical inventory of the LIFEPAK® 10 was completed per the manufacturer's equipment list.

2.1.3.2 An operational validation test of the LIFEPAK® 10 was conducted per the manufacturer's operating instructions by USAARL's medical maintenance personnel.

2.1.4 Test findings

2.1.4.1 The LIFEPAK® 10 was inventoried and found to be complete.

2.1.4.2 The LIFEPAK® 10 operated as prescribed in the manufacturer's operating manual P/N 805057-00. Criteria met.

2.2 BATTERY LIFE EVALUATION (Laboratory)

2.2.1 Objective

To ensure the equipment will function as designed throughout the rated battery operation time.

2.2.2 Criterion

Verify manufacturer's specified full power battery life expectancy of 45 minutes during continuous monitoring of a simulated ECG rate of 60 beats per minute (BPM).

2.2.3 Test procedure

2.2.3.1 Charging and operation cycles were conducted in ambient room conditions of 23°C, 40-60 percent relative humidity (RH).

2.2.3.2 The LIFEPAK® 10 was operated continuously using its three nickel-cadium (NiCad) batteries. The ECG simulator was set to 60 BPM and the CRT display was set for a 1.5 cm 'R' wave display. Monitoring was continued until all three batteries were depleted. Depletion times for individual batteries were noted.

2.2.3 Test findings

The test was conducted using three fully charged batteries. The average operating time in testing was 1 hour and 51 minutes at room temperature (75°F and 55 percent RH). This exceeds manufacturer specification. Although no recharge time was specified in the manufacturer's manuals, the batteries were recharged in 90 minutes in the laboratory. Criterion met.

2.3 ELECTRICAL SAFETY EVALUATION

2.3.1 Objective

To ensure the electrical safety, by evaluation of case-to-ground resistance and case-to-ground current leakage, of the LIFEPAK® 10.

2.3.2 Criterion

The LIFEPAK® 10 shall meet the standards established in National Fire Protection Association (NFPA) 99 for electrical safety of medical equipment.

2.3.3 Test procedure

Measurements in the electrical safety evaluation were made, with a Neurodyne-Dempsey model 431F electrical safety analyzer, in accordance with the procedures described in Technical Bulletin (TB) Number 38-750-2. Case-to-ground resistance and various case-to-ground leakage currents were measured. Leakage currents were measured using a 10 by 20 centimeter aluminum foil sheet taped flush to the equipment case. Checks were made for safety concerns such as case integrity, breaks in power cord insulation, and connectors.

2.3.4 Test findings

Grounding conductor resistance was 41.3 milliohms and maximum case leakage current was 11.6 microamperes. Measurements were taken only on the battery charger unit for the LIFEPAK® 10.

External power supply connections for the LIFEPAK® 10 were not included for the shipped unit. These measurements are below the limits specified in NFPA 99.

2.4 HUMAN FACTORS EVALUATION (Laboratory)

2.4.1 Objectives

2.4.1.1 To assure the safety of the operator, the potential patient, and the aircrew.

2.4.1.2 To assess the design considerations which could potentially contribute to an operator error.

2.4.2 Criterion

The LIFEPAK® 10 must be rated satisfactory in all major categories of the evaluation. These include visual displays, controls, maintainability, conductors, fasteners, test points, test equipment, fuses and circuit breakers, labels and coding, and safety.

2.4.3 Test procedure

2.4.3.1 The evaluation was conducted in a laboratory under fluorescent lighting and ambient room conditions.

2.4.3.2 The LIFEPAK® 10 was operated according to prescribed instructions through its full range of functions.

2.4.4 Test finding

The LIFEPAK® 10 was found to be unsatisfactory in one of the evaluation criteria: Conductors. The coiled cables connecting the paddles to the defibrillator interfere with the replacement of the paddles in their storage spaces. The two coiled cables cannot be stacked in the space between the paddle holders. There is no provision for holding these cables in place vertically while paddles are in use. Therefore, the cables are free to move into the spaces designed for paddle storage. Criterion partially met.

2.5 ALTITUDE (LOW PRESSURE) TEST [IAW MIL-STD-810D, METHOD 500.2]

2.5.1 Objective

To determine if the LIFEPAK® 10 can function as designed in a low pressure environment.

2.5.2 Criterion

The LIFEPAK® 10 will display consistent and accurate measurement of simulated ECG signals within ± 2 percent and deliver the programmed defibrillator energy within 1 percent while exposed to an altitude equivalency of 15,000 feet above sea level.

2.5.3 Test procedure

2.5.3.1 A pretest performance check was conducted to ensure proper operation of the LIFEPAK® 10.

2.5.3.2 The altitude test was performed in a Tenney Engineering model 64S altitude chamber. This test is based on MIL-STD-810D, Method 500.2. The LIFEPAK® 10 was placed in operation near the center of the floor of the chamber. The LIFEPAK® 10 was turned on by means of an armature through the chamber wall and made to monitor a signal from an ECG simulator during the test. The defibrillator was not discharged during this test because there are no provisions for operation from outside the chamber. Chamber pressure was decreased to 420 mm Hg (15,000 ft equivalent altitude) over a 15-minute period, held constant for 60 minutes, then raised, at 1500 fpm, to ambient conditions (760 mm Hg) over a 10-minute period. There are no provisions for the control of temperature or humidity inside this chamber.

2.5.3.3 A posttest performance check was conducted to ensure proper operation of the LIFEPAK® 10 after the exposure to low pressure.

2.5.4 Test findings

2.5.4.1 The pretest performance check met criterion 2.1.2.2.

2.5.4.2 No failures in the performance of the LIFEPAK® 10 were noted before, during, or after the altitude test. Criterion met.

2.5.4.3 The posttest performance check met criterion 2.1.2.2.

2.6 VIBRATION TEST [IAW MIL-STD-810D, METHOD 514.3]

2.6.1 Objective

To determine the ability of the LIFEPAK® 10 to withstand the vibrational stresses expected in a rotary-wing environment without degradation or malfunction.

2.6.2 Criterion

While exposed to vibrational stresses, the LIFEPAK® 10 will remain operational and be able to display consistent and accurate measurement of simulated ECG signals within ± 2 percent and deliver the programmed defibrillator energy within 1 percent.

2.6.3 Test procedure

2.6.3.1 A pretest performance check was conducted to ensure proper operation of the LIFEPAK® 10.

2.6.3.2 The vibration test was performed using an Unholtz-Dickey model TA115-40/CSTA vibration test system. It is a single-axis system with an electromagnetic driver unit. The test consisted of sinusoidal vibrations superimposed on random vibrations over a frequency range of 500 Hz, as shown below. These vibrations are derived from measurements taken on the floor under the copilot's seat in a UH-1 helicopter traveling at 120 knots. The reference spectrum breakpoints are from MIL-STD-810D, Method 514.3; reference spectrum levels are based on field measurements with a conservatism factor of 1.5. Independent tests were conducted in the X, Y, and Z axes.

Z-axis

duration: 60 minutes
broadband intensity: 0.4506 G_{rms}
random vibration: initial slope : 99.00 dB/Hz
5 Hz level: 0.00006210 $G_{sqr/Hz}$
100 Hz level: 0.0006210 $G_{sqr/Hz}$
300 Hz level: 0.0006210 $G_{sqr/Hz}$
500 Hz level: 0.00006210 $G_{sqr/Hz}$
final slope: -99.00 dB/oct
sinusoidal vibration: .5450 G_{pk} at 11.25 Hz
.1690 G_{pk} at 22.50 Hz
.1200 G_{pk} at 33.75 Hz
.0310 G_{pk} at 45.00 Hz
.0530 G_{pk} at 56.25 Hz

X and Y axes

duration: 60 minutes each
broadband intensity: 0.3099 G_{rms}
random vibration: initial slope: 99.00 dB/oct
5 Hz level: 0.00002920 $G_{sqr/Hz}$
100 Hz level: 0.0002920 $G_{sqr/Hz}$
300 Hz level: 0.0002920 $G_{sqr/Hz}$
500 Hz level: 0.00002920 $G_{sqr/Hz}$
final slope: -99.00 dB/oct

sinusoidal vibration: .3200 G_{pk} at 11.25 Hz
.0670 G_{pk} at 22.50 Hz
.0950 G_{pk} at 33.75 Hz
.0350 G_{pk} at 45.00 Hz
.0770 G_{pk} at 56.25 Hz

The LIFEPAK® 10 was strapped to the vibration table fixture, and its performance was evaluated before, during, and after exposure to vibration. ECG signals were provided by a Valmedix simulator. Defibrillator discharge energy was measured with a Dynatech Nevada defibrillator analyzer.

2.6.3.3 A posttest performance check was conducted to ensure proper operation of the LIFEPAK® 10.

2.6.4 Test findings

2.6.4.1 The pretest performance check met criterion 2.1.2.2.

2.6.4.2 No failures in the performance of the LIFEPAK® 10 occurred before, during, or after exposure to vibration. Maximum artifact of 1 mm was observed on ECG display and strip chart recordings during vibration exposure in the X and Y axes. Maximum artifact in the Z-axis was 2 mm. These vibration artifacts may obscure fine details (P, Q, and S waves) in a low amplitude ECG signal. However, heart rate and R wave detection were not compromised. Criterion met.

2.6.4.3 The posttest performance check met criterion 2.1.2.2.

2.7 HIGH TEMPERATURE TEST [IAW MIL-STD-810D, METHOD 501.2]

2.7.1 Objective

To determine the ability of the LIFEPAK® 10 to be stored and operated in a high temperature environment.

2.7.2 Criteria

2.7.2.1 During the high temperature operation check, the LIFEPAK® 10 must display consistent and accurate measurement of simulated ECG signals within ± 2 percent and deliver the programmed defibrillator energy within 1 percent.

2.7.2.2 After the high temperature storage cycle, the LIFEPAK® 10 must be able to display consistent and accurate measurement of simulated ECG signals within ± 2 percent and deliver the programmed defibrillator energy within 1 percent.

2.7.3 Test procedure

2.7.3.1 A pretest performance check was conducted to ensure proper operation of the LIFEPAK® 10.

2.7.3.2 The high temperature test was conducted in a Tenney Engineering model ZWUL-10107D walk-in controlled environment chamber. This test is based on MIL-STD-810D, Method 501.2. For the high temperature operation test, the LIFEPAK® 10 was placed in operation on a wire test stand near the center of the environmental chamber. The ECG leads were routed through a portal in the chamber wall to a Valmedix ECG simulator. Defibrillator energy was measured with a Dynatech Nevada defibrillator analyzer. The chamber temperature was raised to 49°C and the humidity was stabilized at a maximum of 20 percent RH within 15 minutes. The environmental control system is capable of regulating temperature within ±2°C and humidity within ±5 percent RH. Temperature and humidity were held constant for 2 hours. At 30-minute intervals, the chamber door was opened briefly to minimize the change in chamber conditions during performance checks. After the operational test, the LIFEPAK® 10 was allowed to return to ambient conditions over a 30-minute period.

2.7.3.3 A posttest performance check was conducted to ensure proper operation of the LIFEPAK® 10.

2.7.3.4 The LIFEPAK® 10 was stored (not operated) at temperatures of 63°C for 1 hour, 71°C for 4 hours, then again at 63°C for 1 hour. The ECG cable was coiled and placed on top of the defibrillator/monitor and the paddles were stored in their holders. The chamber and LIFEPAK® 10 then were returned to ambient conditions over a 30-minute period.

2.7.3.5 A poststorage performance check was conducted to ensure proper performance of the LIFEPAK® 10.

2.7.4 Test findings

2.7.4.1 The pretest performance check met criterion 2.1.2.2.

2.7.4.2 No operational failures occurred during the high temperature test. Criterion met.

2.7.4.3 The posttest performance check met criterion 2.1.2.2.

2.7.4.4 The LIFEPAK® 10 functioned properly after the high temperature storage test. Criterion met.

2.8 LOW TEMPERATURE TEST [IAW MIL-STD-810D, METHOD 502.2]

2.8.1 Objective

To determine the ability of the LIFEPAK® 10 to be stored and operated in a low temperature environment.

2.8.2 Criteria

2.8.2.1 During the low temperature operation check, the LIFEPAK® 10 must display consistent and accurate measurement of simulated ECG signals within ± 2 percent and deliver the programmed defibrillator energy within 1 percent.

2.8.2.2 After the low temperature storage cycle, the LIFEPAK® 10 must be able to display consistent and accurate measurement of simulated ECG signals within ± 2 percent and deliver the programmed defibrillator energy within 1 percent.

2.8.3 Test procedure

2.8.3.1 A pretest performance check was conducted to ensure proper operation of the LIFEPAK® 10.

2.8.3.2 The LIFEPAK® 10 was placed on the floor of the environmental chamber and the temperature was lowered to 0°C within 25 minutes. The environmental control system is capable of regulating temperature within 2°C. Humidity cannot be controlled in the chamber at freezing temperatures. The temperature was held constant for 2 hours. The chamber door was opened briefly, to minimize the change in chamber conditions, every 30 minutes and a performance check was conducted. The chamber temperature then was raised to ambient temperature within a 30-minute period.

2.8.3.3 A posttest performance check was conducted to ensure proper operation of the LIFEPAK® 10.

2.8.3.4 The LIFEPAK® 10 was "stored" in a nonoperational mode with the power cord coiled and placed on top of the LIFEPAK® 10. The LIFEPAK® 10 was placed on the floor of the environmental test chamber and the temperature was lowered to -46°C for 6 hours. The chamber then was raised to ambient temperature over a 30-minute period.

2.8.3.5 A poststorage performance check was conducted to ensure proper operation of the LIFEPAK® 10.

2.8.4 Test findings

2.8.4.1 The pretest performance check met criterion 2.1.2.2.

2.8.4.2 No operational failures occurred during the low temperature test. Criterion met.

2.8.4.3 The posttest performance check met criterion 2.1.2.2.

2.8.4.4 The LIFEPAK® 10 functioned properly after the low temperature storage test. Criterion met.

2.9 HUMIDITY TEST [IAW MIL-STD-810D, METHOD 507.2]

2.9.1 Objective

To determine the ability of the LIFEPAK® 10 to operate satisfactorily for short periods of time during exposure to highly humid conditions.

2.9.2 Criterion

While exposed to a high humidity environment, the LIFEPAK® 10 must display consistent and accurate measurement of simulated ECG signals within ± 2 percent and deliver the programmed defibrillator energy within 1 percent.

2.9.3 Test procedure

2.9.3.1 A pretest performance check was conducted to ensure the proper operation of the LIFEPAK® 10.

2.9.3.2 The humidity test was conducted in a Tenney Engineering model ZWUL-10107D walk-in controlled environment chamber. This test is based on MIL-STD-810D, Method 507.2. For the humidity test, the LIFEPAK® 10 was placed in operation on a wire test stand near the center of the environmental chamber. The ECG leads were routed through a portal in the chamber wall to a Valmedix ECG simulator. Defibrillator energy levels were measured with a Dynatech Nevada defibrillator analyzer. The chamber temperature was raised to a temperature of 29.5°C and a relative humidity of 95 percent within 25 minutes. Temperature and relative humidity were maintained for 4 hours. The environmental control system is capable of regulating temperature within ±2°C and humidity within ±5 percent RH. At 45-minute intervals the defibrillator/monitor performance was checked. The chamber door was opened briefly to minimize the change in chamber conditions. The chamber and the LIFEPAK® 10 were returned to ambient conditions before the posttest performance validation check was conducted.

2.9.3.3 A posttest performance check was conducted to ensure the proper operation of the LIFEPAK® 10.

2.9.4 Test findings

2.9.4.1 The pretest performance check met criterion 2.1.2.2.

2.9.4.2 No failures were noted in the LIFEPAK® 10 performance checks conducted during the exposure to the high humidity environment. Criterion met.

2.9.4.3 The posttest performance check met criterion 2.1.2.2.

2.10 ELECTROMAGNETIC CHARACTERISTICS TEST [IAW MIL-STD-461A, Notice 4, MIL-STD-462, Notice 3, and MIL-STD-704C]

2.10.1 Objectives

2.10.1.1 To assess the maximum levels of radiated electromagnetic emissions produced by the LIFEPAK® 10 in the 14 kHz to 1.0 GHz frequency range.

2.10.1.2 To assess the tolerances of radiated electromagnetic susceptibility of the LIFEPAK® 10 within the 10 kHz to 10 GHz broadband electric field and the 14 kHz to 12.4 GHz narrowband.

2.10.2 Criteria

2.10.2.1 The LIFEPAK® 10 shall not produce emissions in excess of the limits set forth in MIL-STD-461A, Notice 4, paragraph 6.13.

2.10.2.2 The LIFEPAK® 10 shall not malfunction when it is subjected to radiated emissions as specified in MIL-STD-461A, Notice 4, paragraph 6.20.

2.10.3 Test procedure

2.10.3.1 The radiated emissions test was performed according to MIL-STD-462, Notice 3, Method RE02. The LIFEPAK® 10 was positioned on a wooden test stand 1 meter tall, 0.18 meters wide, and 0.21 meters long, inside the EMI chamber. The unit was directly in line with, and at a horizontal distance of 1 meter from the receiving antennas. The antennas were mounted for both vertical and horizontal polarities and connected to the appropriate EMI receivers. Electrometrics EMC-25 and EMC-50 receivers were used for this test. Their frequency ranges in testing are 14 kHz to 1 GHZ and 1 to 12.4 GHz. Broadband and narrowband detection methods were used from 14 kHz to 1 GHz. Narrowband detection methods were used from 1 GHz to 12.4 GHz. The monitor operated continuously while displaying ECG signals provided by a Valmedix ECG simulator. The defibrillator was charged to 100 joules and discharged into a Dynatech Nevada defibrillator analyzer at 20-second intervals.

2.10.3.2 The radiated susceptibility test was performed according to MIL-STD-462, Notice 3, Method RS03. The LIFEPAK® 10 was positioned on a wooden test stand 1 meter tall, 0.18 meters wide, and 0.21 meters long, inside the EMI chamber. The unit was directly in line with, and at a horizontal distance of 1 meter from the transmitting antennas. The antennas were mounted for both vertical and horizontal polarities and connected to radio frequency (RF) transmitters. The defibrillator/monitor was exposed to fields of 10 V/m from 200 MHz to 2 GHz, and 5 V/m from 2 to 10 GHz. The LIFEPAK® 10 was not tested in the frequency range 10 kHz to 200 MHz because the transmitter necessary for these frequencies was out for repair. All RF carrier waves were 50 percent amplitude modulated with a 1000 Hz tone. The ECG leads were routed through a wave guide tube through the chamber wall. ECG signals were provided by a Valmedix ECG simulator. The defibrillator was in standby mode during this test.

2.10.4 Test findings

2.10.4.1 During the radiated emissions test, narrowband and broadband emissions which exceeded specification limits of MIL-STD-461, Notice 4, were detected in the frequency ranges below.

Frequency	Amount of failure
191 kHz - 3.83 MHz	3.8 - 40.6 dB (NB)
7.46 - 829.82 MHz	1.4 - 48.1 dB (NB)
191 kHz - 3.83 MHz	0.9 - 24.5 dB (BB)
200 - 875 MHz	1.9 - 39.4 dB (BB)

Criterion partially met.

2.10.4.2 The LIFEPAK® 10 was not found to be susceptible to any fields generated during this test. No abnormalities were noticed in defibrillator/monitor operation as a result of exposure to the test fields. Criterion met.

2.11 IN-FLIGHT HUMAN FACTORS EVALUATION

2.11.1 Objective

To assess the physical and/or functional compatibility of the LIFEPAK® 10 while in use onboard the aircraft.

2.11.2 Criterion

The flight surgeon shall be able to operate the LIFEPAK® 10 without physical or functional restrictions aboard the aircraft. Major areas of concern include: Proper operation, visual displays, controls, maintainability, conductors, fasteners, test

points, test equipment, fuses and circuit breakers, labels and coding, and safety.

2.11.3 Test procedure

2.11.3.1 A human factors evaluation was performed in accordance with MIL-STD-1472D, McCormick's Human Factors Evaluation Guide, and UL-544 to ensure the compatibility of the LIFEPAK® 10 and the in-flight environment. The flight surgeon conducted the test wearing a flight suit, flight gloves, and an SPH-4 flight helmet. An evaluation of the compatibility with the nuclear, biological, and chemical (NBC) protective equipment was not conducted. Due to restrictions of the AWR, testing was conducted during daylight hours only.

2.11.3.2 The LIFEPAK® 10 was placed on the top pan of the litter carousel which was configured for four patients. The litter carousel was flown in the "load" position (perpendicular to the long axis of the helicopter). The LIFEPAK® 10 was tested in both the defibrillation and monitoring modes in all flight scenarios required by the In-Flight Test Operations Procedures (ITOP) (refer to section 3.2).

2.11.4 Test findings

During the in-flight human factors evaluation, the LIFEPAK® 10 was found to be satisfactory in all but two categories of the evaluation criteria. First, the deficiency noted in the laboratory evaluation (paragraph 1.5.1.3) was exacerbated by the cramped quarters in the aircraft. Second, the flight surgeon was unable to hear the audio alarms while wearing the required flight ensemble. However, all audio alarms on the LIFEPAK® 10 are backed up by visual alarms which are acceptable. Criterion partially met.

2.12 IN-FLIGHT EMI/EMC CHARACTERISTICS

2.12.1 Objective

To assess the EMI/EMC characteristics of the LIFEPAK® 10 with the host aircraft and its installed systems.

2.12.2 Criteria

2.12.2.1 The LIFEPAK® 10 shall not radiate EMI to disrupt or interfere with other equipment or systems aboard the aircraft.

2.12.2.2 The aircraft shall not radiate EMI to disrupt or interfere with the LIFEPAK® 10's operation.

2.12.3 Test procedure

A qualitative EMI/EMC assessment was performed with both the LIFEPAK® 10 and the aircraft operating as source and victim. The LIFEPAK® 10 and applicable aircraft instruments and systems were monitored for unusual operation, readings, surges, or power anomalies for each checklist item (see pages 3-5 through 3-8).

2.12.4 Test findings

2.12.4.1 There were no adverse instances of EMI/EMC noted with the LIFEPAK® 10 acting as either the source or victim. Criterion met.

2.12.4.2 There were no adverse instances of EMI/EMC noted with the aircraft acting as either the source or victim. Criterion met.

SECTION 3. SUPPORTING DOCUMENTATION

3.1 DETAILED TEST INFORMATION

3.1.1 General information

3.1.1.1 LIFEPAK® 10 testing is not considered a major action significantly affecting the quality of the human environment and therefore qualifies for categorical exclusion A-28, appendix A, AR 200-1.

3.1.1.2 A safety pilot will be designated for each flight. Flight operations will be conducted in accordance with (IAW) the aircraft operator's manual, appropriate aircrew training manuals, and test item technical data.

3.1.2 Material description

3.1.2.1 The Physio Control LIFEPAK® 10 is a portable defibrillator, monitor, and optional noninvasive pacer. The LIFEPAK® 10 is powered from one of the three rechargeable "FASTPAK" NiCad batteries included in the unit. Power is controlled with a green, five-position rotary switch labeled "1 POWER" located on top of the unit case. The rotary switch allows the operator to select one of the three batteries or an optional auxiliary external power source labeled "AUX" (not included in testing). Each battery select switch position has an adjacent red lamp that flashes to indicate a low battery or is continuously illuminated to indicate a depleted battery.

The electrocardiograph (ECG) monitor has a nonfade cathode ray tube (CRT) cardioscope which displays real time ECG. Digital indications of heart rate are displayed on a liquid crystal display (LCD). Two rocker switches, spring-loaded center-off, on the front panel of the monitor are labeled, "ECG SIZE" and "QRS VOLUME". Depressing the left side of the switches decreases ECG size or QRS volume and depressing the right side of the switches increases the ECG size or QRS volume. A pushbutton on/off switch labeled "CAL" on the front panel superimposes a 1 mV pulse on the cardioscope and recorder traces. A pushbutton on/off switch labeled "LEAD SELECT" on the front panel allows the operator to select the ECG input mode. Pressing the "LEAD SELECT" button will advance the input mode through paddles, lead I, lead II, and lead III. A pushbutton on/off switch labeled "RECORDER" on the front panel activates and deactivates the thermal array recorder on top of the monitor. This recorder operates in a 3-second delay mode. A pushbutton on/off switch labeled "CODE SUMMARY" on the front panel activates and deactivates the thermal array recorder to provide printed documentation of critical events on the strip chart. A pushbutton on/off switch labeled "FREEZE" on

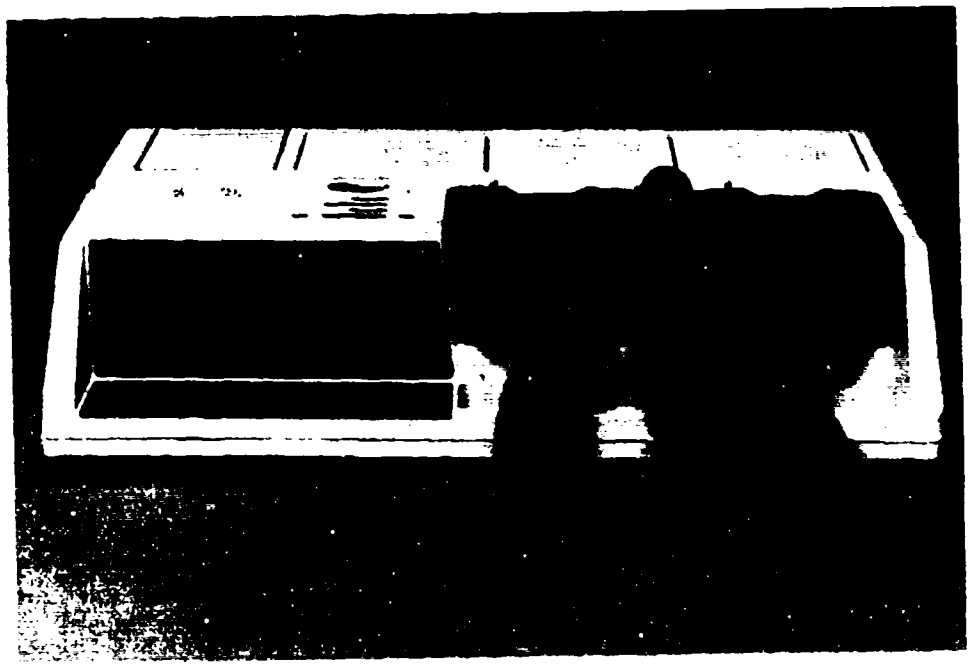
the front panel allows the operator to freeze the trace on the cardioscope as long as the pushbutton is held down. A pushbutton switch labeled "SYNC" on the front panel selects the synchronized discharge mode of defibrillation and "SYNC" is displayed on the LCD. Patient connection is made through a 6-pin Physio Control patient cable connector.

The defibrillator paddles are stored horizontally in slots on the front panel. Nine energy levels of 0, 5, 10, 20, 50, 100, 200, 300, and 360 joules are selected by a rotary switch labeled "2 ENERGY JOULES" located on the sternum (left hand) paddle. A round, yellow pushbutton switch on the apex (right hand) paddle labeled "CHARGE" allows the operator to initiate the defibrillator charge cycle. A round, grey pushbutton switch on the apex paddle labeled "RECORDER" activates the thermal recorder on the monitor. A digital readout on the LCD indicates available energy when the defibrillator is energized. Round, red pushbuttons on the front of ea addle discharge the defibrillator when they are pressed sim neously.

3.1.2.2 Method of Operation: The LIFEPAK® 10 power switch energizes the monitor and defibrillator. The ECG leads selector will be set for "LEAD II" upon startup. The lead selector mode is displayed on the LCD screen below the heart rate readout. The incoming ECG signal travels through the three-lead ECG cable to the preamp circuitry in the monitor where it is amplified and digitized. The signal then is filtered through the defibrillator/ECG microcomputer which s es the digital ECG waveform to be displayed on the CRT. System integrity is monitored continuously by microprocessors which check read only memory (ROM), random access memory (RAM), and software module check sums. The monitor is controlled by a main control panel with pushbuttons that provide logic signals to an executive microprocessor. The defibrillator operates by reading the selected energy setting from the rotary dial on the sternum paddle when the charge button is pressed. A high voltage capacitor then is charged to the appropriate level. When the selected level has been reached, an audible tone sounds and the yellow charging light emitting display (LED) on the sternum paddle switches from flashing to continuous illumination. When the two round, red discharge buttons -- located on the front of the paddles -- are pressed simultaneously, contacts in the transfer relay deliver high voltage to the paddles. Depressing one discharge button alone will not activate the transfer relay. Selecting another charge level with the rotary dial on the sternum paddle after the capacitor is charged will cause the capacitor to discharge internally. Energy discharge through both paddles is controlled solely by the paddle discharge buttons.

3.2 TEST DATA

3.2.1 Photographic Description



LIFEPAK®10 with paddles stored.

LIFEPAK®10 showing cable interference with paddle replacement.

3.2.2 Aircraft equipment list

Item No.	Nomenclature
1	Receiver radio - R-1496A/ARN-89 (automatic direction finder)
2	Displacement gyro - CN-1314/A
3	Gyro directional - CN-998/ASN-43
4	Signal data converter - CV-3338/ASN-128
5	Receiver - R-2139/ARN-123 (VOR/LOC/MB/GS)
6	Command instrument system processor - 70600-01038-101
7	SAS amplifier - 70901-02908-104 (flight control stability augmentation system)
8	Rate gyro - TRU-2A/A
9	Amplifier, impedance - AM-4859A/ARN-89
10	Cargo hook - FE-7590-145
11	Receiver, radar - RT-1193/ASN-128 (doppler navigation receiver)
13	Barometric altimeter - AAU-31/A-1
14	Barometric altimeter - AAU-32A
15	Receiver/transmitter - RT-1300/ARC-186 (VHF-AM and/or FM radio)
16	UHF-AM radio set - RT-1518/ARC-164
17	Interphone control - C6533/ARC (aircraft intercom control)
18	Receiver/transmitter - RT-1115D/APN-209 (radar altimeter)
19	Indicator altimeter - ID-1917C/APN-209 (radar altimeter)
20	Control radio set - C-7392A/ARN-89 (automatic direction finder)
21	Comparator signal data - CM-482/ARC-186 (comparator for ARC-186)
22	Receiver/transmitter - RT-1296A/APX-100 (transponder with IFF)
23	Computer display unit - CP-1252/ASN-128 (doppler navigation system)
24	Compass set controller - C-8021E/ASN75
25	Magnetic compass - standby - MS-17983-4

3.2.3 In-flight test data card

DATA CARD FORMAT

GUIDELINE FOR DATA COLLECTION

IN-FLIGHT SUITABILITY TEST OF MEDICAL ITEMS

1. Installation/removal.	Suitable Yes	Suitable No	Comments
a. Weight and balance (DD Form 365-4, Clearance Form F).	X		
b. Space/area allocation.			
(1) Operational requirements.	X		
(2) Storage requirements.	X		
c. Interface connections (safe, positive, secure).	X		
d. Installation/removal (expedient/easily achieved).	X		
e. Mounting/final configuration (functional/stable).	X		

2. Operations and performance.	Suitable Yes	Suitable No	Comments
a. Manufacturer's operating instruction.	X		
b. Medical item operation before aircraft runup.	X		
c. System interface during aircraft engine runup and medical item operation (EMI switchology checklist).	X		
(1) Aircraft voltage output.	X		

	Suitable Yes	No	Comments
(2) Flight control function (UH-60).			
(3) Stabilator function (UH-60).	X		
(4) Radio communication vs medical item operation.			
(a) FM	X		
(b) UHF	X		
(c) VHF	X		
(5) Navigation equipment vs medical item operation.			
(a) Transponder	X		
(b) ADF	X		
(c) VOR	X		
(d) DOPPLER	X		
(6) Radar altimeter operation vs medical item operation.	X		
d. System interface during aircraft hover and medical item operation (EMI switchology checklist).			
(1) Voltage output.	n/a		
(2) Radio communication vs medical item operation.			
(a) FM	X		
(b) UHF	X		
(c) VHF	X		

	Suitable Yes	No	Comments
(3) Navigation equipment operation vs medical item operation.			
(a) Transponder	X		
(b) ADF	X		
(c) VOR	X		
(d) DOPPLER	X		
e. Flight mission profile vs medical item operation (EMI switchology checklist).			
(1) Straight and level (1000 ft MSL for 20 minutes).			
(a) Compatibility of flight mode and medical item operation.	X		
(b) Radio communication vs medical item operation.			
a. FM	X		
b. UHF	X		
c. VHF	X		
(2) NOE (20 minutes). compatibility of flight mode and medical item operation.	X		
(3) FM homing (10 minutes).	X		
(4) DOPPLER navigation vs medical item operation.			
(a) Initialize function.	X		
(b) Fix function.	X		
(c) Update function.	X		

	Suitable Yes	Suitable No	Comments
(5) VOR navigation 7000 ft MSL for 20 minutes) vs medical item operation.	X		
(6) ILS approach vs medical item operation.	X		
f. Medical item operation after engine shutdown (external power source).	X		
g. Restrictions to the medical item's use (i.e., electrical connectors).	X		
h. Deviations from the laboratory test results.			
(1) Electrical/ electronic.		None	
(2) Mechanical environment.		None	
(3) Human factors (user interface, controls, markings, lighting, egress).		None	
(4) Safety.		None	

3. Deviations from the in-flight test protocol.

a. The VOR navigation portion of the in-flight test conducted at 2000 feet MSL due to air traffic control clearance.

3.2.4 EMI switchology checklist

EMI SWITCHOLOGY CHECKLIST UH-60 AIRCRAFT

IN-FLIGHT SUITABILITY OF MEDICAL ITEMS

ENG INSTRUMENTS/CDU	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
Fuel quantity	X			
Fuel indicator test	X			
XMSN oil temperature	X			
XMSN oil pressure	X			
#1 engine oil temperature	X			
#2 engine oil temperature	X			
#1 engine oil pressure	X			
#2 engine oil pressure	X			
#1 TGT	X			
#2 TGT	X			
#1 Ng speed	X			
#2 Ng speed	X			
CDU digits on/off	X			
CDU instruments dim	X			

ENG INSTRUMENTS/PLT PDU	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
#1 engine RPM	X			
#2 engine RPM	X			
Rotor RPM	X			
#1 torque	X			
#2 torque	X			

ENG INSTRUMENTS/COPLT PDU	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
#1 engine RPM	X			
#2 engine RPM	X			
Rotor RPM	X			
#1 torque	X			
#2 torque	X			

ENG CONTROLS	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
#1 overspeed	X			
#2 overspeed	X			
RPM switch	X			
#1 engine anti-ice	X			
#2 engine anti-ice	X			
#1 inlet anti-ice	X			
#2 inlet anti-ice	X			

RADIO EQUIPMENT	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
ICS, C-6533 ARC	X			
VHF-FM, ARC-186/115	X			
VHF-AM, ARC-186/115	X			
UHF-AM, ARC-164(V)	X			
Crypto, KY-28	Not installed			
Radio retransmissions PLN	Not installed			
Transponder, APX-100(V)	X			
KIT-1A/TSEC IFF computer	Not keyed with code			

MISSION EQUIPMENT	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
RWR, APR-39(V)	Not installed			
IR CM, ALQ-144	Not installed			
Chaff dispenser, M-130	Not installed			
Cargo hook system	X			

HYDRAULIC CONTROL SYSTEM	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
Backup hydraulic pump	X			
Servo off 1st stage/PLT	X			
Servo off 2nd stage/PLT	X			
Servo off 1st stage/COPLT	X			
Servo off 2nd stage/COPLT	X			
Hydraulic leak test	X			
Tail servo	X			
Boost servos	X			

FUEL SYSTEM	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
Fuel pump switch	X			
Fuel boost pump #1	X			
Fuel boost pump #2	X			
Fuel cont panel ESSS	Not installed			

WARNING SYSTEM	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
Low rotor RPM	X			
Master caution	X			
Caution advisory	X			
Fire warning	X			
AFCS	X			
Stabilator	X			
#1 engine out	X			
#2 engine out	X			

NAVIGATION INSTRUMENTS	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
ADF	X			
Magnetic compass	X			
CONUS NAV, ARN-123	X			
DOPPLER, ASN-128	X			
Gyro mag compass (PLT)	X			
Gyro mag compass (COPLT)	X			
Compass cont panel, ASN-75	X			
HSI	X			

FLIGHT INSTRUMENTS	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
Radar altimeter	X			
Stabilator pos indicator	X			
VSI	X			
CIS mode select	X			
SAS 1	X			
SAS 2	X			
FPS	X			
Trim	X			
Go-around enable	X			
Cyclic trim release	X			
Cyclic stick trim	X			
ALR encoder	X			

FLIGHT INSTRUMENTS (CONT)	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
HSI/VSI mode select (PLT)				
DPLR	X			
VOR/ILS	X			
BACK CRS	X			
FM HOME	X			
TURN RATE	X			
CRS HDG	X			
VERT GYRO	X			
BRG 2	X			
HSI/VSI Mode Select (COPLT)				
DPLR	X			
VOR/ILS	X			
BACK CRS	X			
FM HOME	X			
TURN RATE	X			
CRS HDG	X			
VERT GYRO	X			
BRG 2	X			

MISCELLANEOUS EQUIPMENT	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
Blade de-ice	Not tested			Ambient temperature was out of test limits.
Windshield anti-ice	X			
Pilot heat	X			
Vent blower	X			
Windshield wiper	X			
Heater	X			
APU	X			
Generator #1	X			
Generator #2	X			
Generator APU	X			
Air source heat start	X			
Tail wheel lock	X			
Gyro erect	X			

LIGHTING	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
Cockpit utility	X			
Cockpit flood	X			
Cabin dome	X			
Search light	X			
Search light control	X			
Landing light	X			
Flt instr lights (PLT)	X			
Flt instr lights (COPLT)	X			
Nonflight instr lights	X			
Console lights, upper	X			
Console lights, lower	X			
Position lights	X			
Formation lights	X			
Anticollision lights	X			
NVG lighting	X			

3.2.5 Battery life evaluation

Battery Life Evaluation
Report Form

Nomenclature: Defibrillator/Monitor
Manufacturer: Physio Control
Model number: LIFEPAK® 10
Serial number: 00004322
Military item number: None

Options installed: None

Manufacturer battery life specification:
45 minutes in monitor mode
Specified battery recharge time:
none; information not provided in manuals
Specified mode of operation under battery power:
monitoring of ECG signal at 60 BPM
Overall performance: Pass

Measurements:

Dates of first test:	27 Dec 90
Temperature:	22°C
Humidity:	50% RH
Start times:	0902
End times:	1059
Operating times:	1 hour 57 minutes
**********	
Total operating time:	1 hour 57 minutes
Performance:	Pass

Dates of second test:	27 Dec 90
Temperature:	23°C
Humidity:	65% RH
Start times:	0927
End times:	1118
Operating times:	1 hour 51 minutes
**********	
Total operating time:	1 hour 51 minutes
Performance:	Pass

Dates of third Test:	27 Dec 90
Temperature:	23°C
Humidity:	65% RH
Start times:	1337
End times:	1518
Operating times:	1 hour 41 minutes
**********	
Total operating time:	1 hour 41 minutes
Performance:	Pass

Comments: The unit averaged 1 hour 49 minutes of operation.

3.2.6 Electrical safety test

Electrical Safety Test
Report Form

Nomenclature: Defibrillator/monitor
Manufacturer: Physio Control
Model number: LIFEPAK® 10
Serial number: 00004322
Military item number: None
Line cord identification: Northwire, Inc., 16/3, SJT
Options installed: None

Date of test: 21 Dec 90

Measurements:

Grounding conductor resistance (milliohms): 41.3

Leakage current - Case to ground (microamps):

unit off, grounded, normal polarity	N/A
unit off, ungrounded, normal polarity	N/A
unit off, ungrounded, reverse polarity	N/A
unit on, grounded, normal polarity	5.0
unit on, ungrounded, normal polarity	11.6
unit on, ungrounded, reverse polarity	6.0

MAXIMUM LIMITS:
ground resistance: 150 milliohms
current (grounded, type A unit): 10
current (ungrounded, type A unit): 100
current (grounded, type B unit): 50
current (ungrounded, type B unit): 500

Comments on item set-up or checks:

The test was conducted on the battery charger. The charger does not have a power switch (always on when plugged in). The defibrillator/monitor is completely battery powered with no external power conductors.

Comments on test run (including interruptions):

Metal foil was used for leakage current tests on the charger. It does not have an external grounded metal surface. The ground conductor resistance was measured at the AC cord connector.

Comments on other data:

Additional tests for defibrillators

Current to paddles ( ), EUT off: N/A
(G, NP) (UG, NP) (UG, RP)

Current to paddles ( ), EUT on: N/A
(G, NP) (UG, NP) (UG, RP)

Output energy (watt-seconds):

Control setting	Energy indicated	Energy delivered	(Battery)
10	10	N/A	10
20	20	N/A	20
50	50	N/A	50
100	100	N/A	101
200	200	N/A	196
300	300	N/A	296
360	360	N/A	354

Maximum time to full charge (seconds), AC: N/A DC: 10
Maximum time for synchronized discharge (mS): 27

Comments on item set-up or checks:

Comments on test run (including interruptions):

Comments on other data:

3.2.7 Human factors evaluation

Human Factors Evaluation
Report Form

Nomenclature: Defibrillator/Monitor
Manufacturer: Physio Control
Model number: LIFEPAK® 10
Serial number: 00004322
Military item number: None

Options installed: None

Date of test: 27 Dec 90

Item configuration during test:

Prepared for operation, sitting on a countertop.

Checklist for HFE

RESULTS

VISUAL DISPLAYS: **Satisfactory**

PASS: display type, format, content
PASS: location of displays
PASS: indicator lights
PASS: scalar displays
PASS: color coding
PASS: legends and labels
PASS: cathode ray tubes
PASS: counters
PASS: flags, go/no go, center-null indicators

Comments:

CONTROLS: **Satisfactory**

PASS: location
PASS: characteristics of controls
PASS: labeling
PASS: control - display relationships

Comments:

TIME REQUIRED TO PREPARE FOR OPERATION (list in comment)

Comments: Approximately 10 minutes

MAINTAINABILITY: Satisfactory

PASS: component location
PASS: component characteristics
PASS: rests & stands
PASS: covers, cases, access doors
PASS: handles
N/A : lubrication
PASS: component mounting
PASS: cord storage provisions
PASS: external accessibility
PASS: internal accessibility
NONE: list special tools required
* : list realistic inspection requirements
** : list realistic inspection intervals

Comments: * daily check of operation and accessories
** quarterly preventive maintenance

CONDUCTORS: Unsatisfactory

PASS: binding & securing
PASS: length
PASS: protection
FAIL: routing
PASS: conductor coding
PASS: fabrication
PASS: connectors

Comments: Paddle cables interfere with the replacement of the paddles in their storage area.

FASTENERS: Satisfactory

PASS: access through inspection panel covers
PASS: enclosure fasteners
PASS: device mounting bolts & fasteners

Comments:

TEST POINTS: N/A

N/A : general
N/A : location & mounting
N/A : test point labeling & coding

Comments:

TEST EQUIPMENT: Satisfactory

PASS: general
PASS: equipment self-test
PASS: indicators (list in comments)
PASS: controls
PASS: positive indication of proper operation

Comments: All segments of the display screen are illuminated during the self-test. Failure is visible if the self-test finds an error.

FUSES & CIRCUIT BREAKERS: Satisfactory

PASS: external accessibility
PASS: easy replacement or reset by operator

Comments: A fuse is accessible on the battery charger only; fuses on the defibrillator/monitor are internal.

LABELS & CODING: Satisfactory

PASS: placed above controls and displays
PASS: near or on the items they identify
PASS: not obscured by other equipment components
PASS: describe the function of the items they identify
PASS: readable from normal operating distance
PASS: conspicuous placards adjacent to hazardous items

Comments:

SAFETY: **Satisfactory**

PASS: manual
PASS: materials
PASS: fire & explosive protection
PASS: operator protection from mechanical hazards
PASS: patient protection from mechanical hazards
PASS: electrical safety (operator and patient)

Comments:

3.2.8 Altitude test

Altitude Test
Report Form

Nomenclature: Defibrillator/Monitor
Manufacturer: Physio Control
Model number: LIFEPAK® 10
Serial number: 00004322
Military item number: None

Options installed: None

Date of test: 26 Dec 90

Item configuration during test:

Operating on the chamber floor with a simulated ECG signal of 60 BPM.

Performance test criteria:

Consistent and accurate measurements of simulated ECG signals and correct delivery of programmed defibrillator energy.

Ambient conditions outside chamber:

Temperature	75°F
Humidity	50% RH
Barometric pressure	1 atm

PRETEST DATA

Pretest performance check:

Item functional (based on performance test criteria)	All OK Pass

Installation of item in test facility:

list connections to power	None
list connections to simulators	Valmedix ECG
list connections to dummy loads	None
list unconnected terminals	Pace and Aux. outlets

IN-TEST DATA

Time of test start: 14:00

POSTTEST DATA

Posttest performance check :
(complete check of item and accessories)
Time of test end : 15:00
Item functional (based on performance test criteria)
All OK Pass
Deviation from pretest: None

Comments on item set-up or checks:

Comments on test run (including interruptions):

Comments on other data:

3.2.9 Vibration test

Vibration Test
Report Form

Nomenclature: Defibrillator/Monitor
Manufacturer: Physio Control
Model number: LIFEPAK® 10
Serial number: 00004322
Military item number: None

Options installed: None

Date of test: 26 Dec 90

Item configuration during test:

Strapped down on vibration table fixture.

Performance test criteria:

Consistent and accurate measurement of simulated ECG signals and correct delivery of programmed defibrillator energy.

PRETEST DATA

Pretest performance check :
Item functional (based on performance test criteria) All OK Pass

Installation of item in test facility:

list connections to power	None
list connections to simulators	Defibrillator Analyzer, Valmedix ECG
list connections to dummy loads	None
list unconnected terminals	Pace and Aux. outlets

Ambient conditions

Temperature	70°F
Humidity	50% RH
Barometric pressure	1 atm

IN-TEST DATA

Data and performance checks during test:

Times and dates of test start
X: 12/26/90, 0910 Y: 12/26/90, 1015 Z: 12/26/90, 1233

Time at first check:
X: 0920 Y: 1020 Z: 1242
Item functional (based on performance test criteria)
All OK Pass
Deviation from pretest: None

Time at second check:
X: 1002 Y: 1107 Z: 1330
Item functional (based on performance test criteria)
All OK Pass
Deviation from pretest: None

POSTTEST DATA

Time at test end:
X: 1005 Y: 1115 Z: 1333
Posttest performance check:
(complete check of item and accessories)
Item functional (based on performance test criteria)
All OK Pass
Item intact: Yes
Deviation from pretest: None

Comments on item set-up or checks:

Comments on test run (including interruptions):

Comments on other data:

3.2.10 High temperature test

High Temperature Test
(equipment operating)
Report Form

Nomenclature: Defibrillator/Monitor
Manufacturer: Physio Control
Model number: LIFEPAK® 10
Serial number: 00004322
Military item number: None

Options installed: None

Date of test: 22 Dec 90

Item configuration during test:

Operating on wire test stand in the center of the chamber.

Performance test criteria:

Consistent and accurate measurement of simulated ECG signals and correct delivery of programmed defibrillator energy.

Ambient conditions outside chamber:

Temperature	23°C
Humidity	54% RH
Barometric pressure	1 atm

PRETEST DATA

Pretest performance check :
Item functional (based on performance test criteria) All OK Pass

Installation of item in test facility:

list connections to power	None
list connections to simulators	Defibrillator Analyzer, Valmedix ECG
list connections to dummy loads	None
list unconnected terminals	Pace and Aux. outlets

distance from north wall (meters)	0.57
distance from south wall (meters)	0.57
distance form east wall (meters)	1.22
distance from west wall (meters)	1.38
distance from ceiling (meters)	1.50
distance from floor (meters)	0.50

Time of test start: 7:55

Performance checks during test:

First check:

Time:	8:25
Temperature:	49°C ± 1°C
Humidity:	15% RH ± 1% RH
Barometric pressure:	1 atm

Item functional (based on performance test criteria) All OK Pass

Deviation from pretest: None

Second check:

Time:	8:55
Temperature:	49°C ± 1°C
Humidity:	15% RH ± 1% RH
Barometric pressure:	1 atm

Item functional (based on performance test criteria) All OK Pass

Deviation from pretest: None

Third check:

Time:	9:25
Temperature:	49°C ± 1°C
Humidity:	15% RH ± 1% RH
Barometric pressure:	1 atm

Item functional (based on performance test criteria) All OK Pass

Deviation from pretest: None

POSTTEST DATA

Posttest performance check:
(complete check of item and accessories)
Time of test end: 9:55
Item functional: (based on performance test criteria)
All OK Pass
Deviation from pretest: None

Comments on item set-up or checks:

Comments on test run (including interruptions):

Comments on other data:

3.2.11 High temperature storage test

High Temperature Test
(equipment in storage)
Report Form

Nomenclature: Defibrillator/Monitor
Manufacturer: Physio Control
Model number: LIFEPAK® 10
Serial number: 00004322
Military item number: None

Options installed: None

Date of test: 22 Dec 90

Item configuration during test:

Sitting on wire test stand in the center of the chamber. The unit is in storage, not operating.

Performance test criteria:

Consistent and accurate measurement of simulated ECG signals and correct delivery of programmed defibrillator energy.

Ambient conditions outside chamber:

Temperature	23°C
Humidity	54% RH
Barometric pressure	1 atm

PRETEST DATA

Pretest performance check:
Item functional (based on performance test criteria) All OK Pass

Installation of item in test facility:

list connections to power	None
list connections to simulators	None
list connections to dummy loads	None
list unconnected terminals	All (Pace and Aux.)

distance from north wall (meters) 0.57
distance from south wall (meters) 0.57
distance form east wall (meters) 1.22
distance from west wall (meters) 1.38
distance from ceiling (meters) 1.50
distance from floor (meters) 0.50

Time of test start: 10:25
Midtest time: 13:25
Midtest temperature: 49°C ± 1°C
Midtest humidity: 15% RH ± 1% RH

POSTTEST DATA

Posttest performance check:
(complete check of item and accessories)
Time of test end: 16:25
Item functional (based on performance test criteria)
All OK Pass
Deviation from pretest: None

Comments on item set-up or checks:

Comments on test run (including interruptions):

Comments on other data:

3.2.12 Low temperature test

Low Temperature Test
(equipment operating)
Report Form

Nomenclature: Defibrillator/Monitor
Manufacturer: Physio Control
Model number: LIFEPAK® 10
Serial number: 00004322
Military item number: None

Options installed: None

Date of test: 23 Dec 90

Item configuration during test:

Operating on the wire test stand in the center of the chamber.

Performance test criteria:

Consistent and accurate measurement of simulated ECG signals and correct delivery of programmed defibrillator energy.

Ambient conditions outside chamber:

Temperature	24°C
Humidity	58% RH
Barometric pressure	1 atm

PRETEST DATA

Pretest performance check:
Item functional (based on performance test criteria) All OK Pass

Installation of item in test facility:

list connections to power	None
list connections to simulators	Defibrillator Analyzer, Valmedix ECG
list connections to dummy loads	None
list unconnected terminals	Pace and Aux. outlets

distance from north wall (meters) 0.57
distance from south wall (meters) 0.57
distance form east wall (meters) 1.22
distance from west wall (meters) 1.38
distance from ceiling (meters) 1.50
distance from floor (meters) 0.50

Time of test start: 7:55

Performance checks during test:

First check:

Time: 8:25
Temperature: 0.0°C ± 1° C
Humidity: n/a
Barometric pressure: 1 atm
Item functional (based on performance test criteria)
All OK Pass
Deviation from pretest: None

Second check:

Time: 8:55
Temperature: 0.0°C ± 1°C
Humidity: n/a
Barometric pressure: 1 atm
Item functional (based on performance test criteria)
All OK Pass
Deviation from pretest: None

Third check:

Time: 9:25
Temperature: 0.0°C ± 1°C
Humidity: n/a
Barometric pressure: 1 atm
Item functional (based on performance test criteria)
All OK Pass
Deviation from pretest: None

POSTTEST DATA

Posttest performance check:
(complete check of item and accessories)
Time of test end: 9:55
Item functional (based on performance test criteria)
All OK Pass
Deviation from pretest: None

Comments on item set-up or checks:

Comments on test run (including interruptions):

Comments on other data:

3.2.13 Low temperature storage test

Low Temperature Test
(equipment in storage)
Report Form

Nomenclature: Defibrillator/Monitor
Manufacturer: Physio Control
Model number: LIFEPAK® 10
Serial number: 00004322
Military item number: None

Options installed: None

Date of test: 23 Dec 90

Item configuration during test:

Sitting on wire test stand in the center of the chamber. The unit is in storage, not operating.

Performance test criteria:

Consistent and accurate measurement of simulated ECG signals and correct delivery of programmed defibrillator energy.

Ambient conditions outside chamber:

Temperature	24°C
Humidity	58% RH
Barometric pressure	1 atm

PRETEST DATA

Pretest performance check:

Item functional (based on performance test criteria)	All OK	Pass

Installation of item in test facility:

list connections to power:	None
list connections to simulators:	None
list connections to dummy loads	None
list unconnected terminals	All (Pace and Aux.)

distance from north wall (meters)	0.57
distance from south wall (meters)	0.57
distance form east wall (meters)	1.22
distance from west wall (meters)	1.38
distance from ceiling (meters)	1.50
distance from floor (meters)	0.50

Time of test start: 10:30
Midtest time: 13:30
Midtest temperature: -46°C ± 1°C

POSTTEST DATA

Posttest performance check:
(complete check of item and accessories)
Time of test end: 15:10
Item functional (based on performance test criteria)
All OK Pass
Deviation from pretest: None

Comments on item set-up or checks:

Comments on test run (including interruptions):

Comments on other data:

The EUT was allowed to return to ambient conditions overnight.

3.2.14 Humidity test

Humidity Test
Report Form

Nomenclature: Defibrillator/Monitor
Manufacturer: Physio Control
Model number: LIFEPAK® 10
Serial number: 00004322
Military item number: None

Options installed: None

Date of test: 24 Dec 90

Item configuration during test:

Operating on the wire test stand in the center of the chamber.

Performance test criteria:

Consistent and accurate measurement of simulated ECG signals and correct delivery of programmed defibrillator energy.

Ambient conditions outside chamber:

Temperature	24°C
Humidity	40% RH
Barometric pressure	1 atm

PRETEST DATA

Pretest performance check:
Item functional (based on performance test criteria) All OK Pass

Installation of item in test facility:

list connections to power	None
list connections to simulators	Defibrillator Analyzer, Valmedix ECG
list connections to dummy loads	None
list unconnected terminals	Pace and Aux. outlets

distance from north wall (meters)	0.57
distance from south wall (meters)	0.57
distance form east wall (meters)	1.22
distance from west wall (meters)	1.38
distance from ceiling (meters)	1.50
distance from floor (meters)	0.50

IN-TEST DATA

Time of test start: 8:10

Performance checks during test:

First check:

Time:	8:55
Temperature:	29.5°C ± 1°C
Humidity:	95% RH ± 1% RH
Barometric pressure:	1 atm

Item functional (based on performance test criteria)
All OK Pass

Deviation from pretest: None

Second check:

Time:	9:40
Temperature:	29.5°C ± 1°C
Humidity:	95% RH ± 1% RH
Barometric pressure:	1 atm

Item functional (based on performance test criteria)
All OK Pass

Deviation from pretest: None

Third check:

Time:	10:25
Temperature:	29.5°C ± 1°C
Humidity:	95% RH ± 1% RH
Barometric pressure:	1 atm

Item functional (based on performance test criteria)
All OK Pass

Deviation from pretest: None

Fourth check:

Time: 11:10
Temperature: 29.5°C ± 1°C
Humidity: 95% RH ± 1% RH
Barometric pressure: 1 atm
Item functional (based on performance test criteria)
All OK Pass
Deviation from pretest: None

Fifth check:

Time: 11:55
Temperature: 29.5°C ± 1°C
Humidity: 95% RH ± 1% RH
Barometric pressure: 1 atm
Item functional (based on performance test criteria)
All OK Pass
Deviation from pretest: None

POSTTEST DATA

Posttest performance check:
(complete check of item and accessories)
Time of test end: 12:25
Item functional (based on performance test criteria)
All OK Pass
Deviation from pretest: None

Comments on item set-up or checks:

Comments on test run (including interruptions):

Comments on other data:

3.2.15 Electromagnetic characteristics test

****

Electromagnetic characteristics testing
evaluation of performance
****

T & E Item Number: 27 Date: 21 Dec 90

Nomenclature: Defibrillator/Monitor Manufacturer: Physio Control

Model number: LIFEPAK® 10 Serial number: 00004322

Military item number: None

****

Conducted emissions tests

CE01 Testing configuration(s): n/a
Performance (pass/fail): n/a
Comments: The unit has no external power leads.

CE02 Testing configuration(s): n/a
Performance (pass/fail): n/a
Comments: The unit has no external power leads.

CE04 Testing configuration(s): n/a
Performance (pass/fail): n/a
Comments: The unit has no external power leads.

Conducted susceptibility tests

CS02 Testing configuration(s): n/a
Performance (pass/fail): n/a
Comments: The unit has no external power leads.

CS06 Testing configuration(s): n/a
Performance (pass/fail): n/a
Comments: The unit has no external power leads.

Radiated emissions tests

RE02 Testing configuration(s): Operating on wooden test stand in the EMC chamber.
Performance (pass/fail): Fail
Comments:

Narrowband failure data	dB of failure
191 kHz - 3.83 MHz	3.8 - 40.6
7.46 MHz - 829.82 MHz	1.4 - 48.1

Broadband failure data	db of failure
191 kHz - 3.83 MHz	0.9 - 24.5
200 MHz - 875 MHz	1.9 - 39.4

Radiated susceptibility tests

RS03 Testing configuration(s): Operating on the wooden test stand in the EMC chamber.
Performance (pass/fail): Pass
Comments:
The unit was not susceptible to the test fields between 200 MHz and 10 GHz.

3.3 CRITERIA, SIGNIFICANT PROBLEMS, AND SUGGESTED IMPROVEMENTS

3.3.1 Criteria

Item No.	Criteria (Source)	Remarks	Applicable subparagraph
1	The physical inventory is conducted solely for investigation and documentation.	N/A	2.1.2.1
2	The LIFEPAK® 10 will display a consistent and accurate measurement of simulated ECG signals within ± 2 percent and deliver the programmed defibrillator energy within 1 percent.	met	2.1.2.2
3	Verify manufacturer's specified full power battery life expectancy of 45 minutes during continuous monitoring of a simulated ECG rate of 60 BPM.	met	2.2.2
4	The LIFEPAK® 10 shall meet the limits established in NAFP 99 for electrical safety of medical equipment.	met	2.3.2
5	The LIFEPAK® 10 must be rated satisfactory in all major categories of the evaluation. These include: Visual displays, controls, maintainability, conductors, fasteners, test points, test equipment, fuses and circuit breakers, labels and coding, and safety.	partially met	2.4.2
6	The LIFEPAK® 10 will display consistent and accurate measurement of simulated ECG signals within ± 2 percent and deliver the programmed defibrillator energy within 1 percent while exposed to an altitude equivalency of 15,000 feet above sea level.	met	2.5.2

7	While exposed to vibrational stresses, the LIFEPAK® 10 will remain operational and be able to display a consistent and accurate measurement of simulated ECG signals within ± 2 percent and deliver the programmed defibrillator energy within 1 percent.	met	2.6.2
8	During the high temperature operation check, the LIFEPAK® 10 must display consistent and accurate measurement of simulated ECG signals within ± 2 percent and deliver the programmed defibrillator energy within 1 percent.	met	2.7.2.1
9	After the high temperature storage cycle, the LIFEPAK® 10 must be able to display consistent and accurate measurement of simulated ECG signals within ± 2 percent deliver the programmed defibrillator energy within 1 percent.	met	2.7.2.2
10	During the low temperature operation check, the LIFEPAK® 10 must be able to display consistent and accurate measurement of simulated ECG signals within ± 2 percent programmed defibrillator energy within 1 percent.	met	2.8.2.1
11	After the low temperature storage cycle, the LIFEPAK® 10 must be able to display consistent and accurate measurement of simulated ECG signals within ± 2 percent and deliver the programmed defibrillator energy within 1 percent.	met	2.8.2.2

12	While exposed to a high humidity environment, the LIFEPAK® 10 must display consistent and accurate measurement of simulated ECG signals within ± 2 percent and deliver the programmed defibrillator energy within 1 percent.	met	2.9.2
13	The LIFEPAK® 10 shall not produce emissions in excess of the limits set forth in MIL-STD-461A Notice 4, paragraph 6.13.	partially met	2.10.2.1
14	The LIFEPAK® 10 shall not malfunction when it is subjected to radiated fields as specified in MIL-STD-461A, Notice 4, paragraph 6.20.	met	2.10.2.2
15	The flight surgeon shall be able to operate the LIFEPAK® 10 without physical or functional restrictions aboard the aircraft.	partially met	2.11.2.1
16	The LIFEPAK® 10 shall not radiate EMI to disrupt or interfere with the other equipment or systems aboard the aircraft.	met	2.12.2.2
17	The aircraft shall not radiate EMI to disrupt or interfere with the LIFEPAK® 10.	met	2.12.2.3

3.3.2 Significant problems which require corrective action

None

3.3.3 Suggested improvements

Suggestion	Applicable Subparagraph
1. A method to channel or contain the defibrillator cables between the paddles needs to be added. This would preclude the cables interference when replacing the paddles in the LIFEPAK® 10.	2.3.4 and 2.10.4

3.4 REFERENCES

3.4.1 Department of Defense. 1971. EMI characteristics, requirements for equipment. Washington, D.C. MIL-STD-461A, Notice 4. February.

3.4.2 Department of Defense. 1971. EMI characteristics, measurement of. Washington, D.C. MIL-STD-462, Notice 3. February.

3.4.3 Department of Defense. 1983. Environmental test methods and engineering guidelines. Washington, D.C. MIL-STD-810D. July.

3.4.4 Department of the Army. 1987. Maintenance management procedures for medical equipment. Washington, D.C. TB 38-750-2. April.

3.4.5 Department of Defense. 1985. Standard general requirements for electronic equipment. Washington, D.C. MIL-STD-454K. February.

3.4.6 Underwriters Laboratory's, Inc. 1978. Standard for safety, medical and dental equipment. Chicago, Illinois. UL-544.

3.4.7 Department of Defense. 1989. Human engineering design criteria for military systems equipment, and facilities. Washington, D.C. MIL-STD-1472D. March.

3.4.8 Association for the Advancement of Medical Instruments. Human factors engineering guidelines and preferred practices for the design of medical devices. Arlington, Virginia. AAMI-HE-1988. February.

3.4.9 Department of the Army. 1978. Operator's manual, UH-60 and EH-60 helicopter, with changes 1-5. Washington, D.C. TM 55-1520-237-10. January.

3.4.10 Department of the Army. 1987. Maintenance management procedures for medical equipment. Washington, D.C. TB 38-750-2. April.

3.4.11 National Fire Protection Association. 1987. Standard for health care facilities. Quincy, Massachusetts. February.

3.4.12 Physio Control. 1989. Operating instructions, LIFEPAK® 10 defibrillator/monitor. Redmond, Washington.

3.4.13 Mitchell, G. W., and Adams, J. E. 1988. Technical test and evaluation of aeromedical equipment. Fort Rucker, AL: U. S. Army Aeromedical Research Laboratory. USAARL Letter Report LR-88-16-1-2.

3.5 ABBREVIATIONS

AVSCOM	Army Aviation Systems Command
AEST	aeromedical equipment suitability test
AWR	airworthiness release
BB	broadband
BPM	beats per minute
CAAF	Cairns Army Airfield
CRT	cathode ray tube
DC	direct current
ECG	electrocardiograph
EMC	electromagnetic compatibility
EMI	electromagnetic interference
fpm	feet per minute
GFE	government furnished equipment
Gpk	gravity, peak
G(rms)	gravity (root mean square)
Hz	hertz
IAW	in accordance with
ITOP	in-flight test operating procedure
IGE	in-ground effect
KHz	kilohertz
KIAS	knots indicated airspeed
LCD	liquid crystal display
LED	light emitting diode
LIFEPAK® 10	Physio Control defibrillator/monitor, model LIFEPAK® 10
MEDEVAC	medical evacuation
MHz	mega hertz
MIL-STD	military standard
ml	milliliter
mm	millimeter
mmHg	millimeters of Mercury
MSL	mean sea level
NAFP	National Association of Fire Prevention
NB	narrowband
NBC	nuclear, biological and chemical
NiCad	nickel cadmium
NVG	night vision goggle

RAM	random access memory
RF	radio frequency
RH	relative humidity
ROM	read only memory
TB	technical bulletin
TFT	technical feasibility testing
T & E	test and evaluation
UES	Universal Energy Systems, Inc.
USAARL	U. S. Army Aeromedical Research Laboratory
V/m	volts per meter